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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,377	06/19/2006	Catherine J. Pachuk	NUCL-006/01US 306512-2111	3823

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COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
5th Floor
1200 19th Street, NW
Washington, DC 20036

EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,377	PACHUK ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *32-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed on June 19, 2006, is acknowledged. Claims 1-31 have been cancelled. Claims 32-98 are pending.

2. It is noted that Claim 96 is missing. Correction is required.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 32-44, and 91, insofar as drawn to a special technical feature of a method and a composition for inhibiting HBV expression *in vivo* using **at least one** or **two** double-stranded RNA effector molecule comprising a sequence selected from the group consisting of SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:49.

Group II, claim(s) 45-52, drawn to a special technical feature of a method and a composition for inhibiting HCV expression *in vivo* using **at least two** double-stranded RNA effector molecules, each double-stranded RNA effector molecule comprising: (a) a sequence selected from the group consisting of SEQ ID NO: 54, SEQ ID NO: 55, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59, and SEQ ID NO:62; (b) the reverse complement of said selected sequence; and (c) optionally, a sequence linking sequences (a) and (b); wherein U is substituted for T.

Group III, claim(s) 53-62, drawn to a special technical feature of a method for inhibiting HCV expression *in vivo* using **at least two** double-stranded RNA effector molecules comprising: (a) an RNA sequence equivalent to HCV coding strand sequence selected from the group consisting of sequence position 9510-9504, (b) their reverse complement; and optionally (c) a linker.

Group IV, claim(s) 63-67 and 78-81, drawn to a special technical feature of a method and a composition for inhibiting HBV expression *in vivo* using a double-stranded RNA effector molecule comprising an at least 19 contiguous base pair nucleotide sequence from within a sequence selected from the group consisting of SEQ ID NO:1-10.

Group V, claim(s) 68-73, 82-84 and 94, drawn to a special technical feature of a method for inhibiting HCV expression *in vivo* using a double-stranded RNA effector molecule comprising an at least 19 contiguous base pair nucleotide sequence from within a sequence selected from the group consisting of SEQ ID NO:11 and SEQ ID NO:12.

Group VI, claim(s) 74-77, and 85-90, drawn to a special technical feature of a method and a composition for inhibiting expression of both HBV and HCV in the same *in vivo* mammalian cell using a double-stranded RNA effector molecule comprising a first at least 19 contiguous base pair nucleotide sequence from within a sequence selected from the group consisting of SEQ ID NO:1-10 and a double-stranded RNA effector molecule comprising a second at least 19 contiguous base pair nucleotide sequence from within a sequence selected from the group consisting of SEQ ID NO:11; SEQ ID NO:12; and SEQ ID NO: 27.

Group VII, claim(s) 91, insofar as drawn to a special technical feature of a polynucleotide sequence comprising a sequence selected from SEQ ID NOs:14-17, 20, 24-26, and SEQ ID NO:49.

Group VIII, claim(s) 92, insofar as drawn to a special technical feature of a polynucleotide sequence comprising nucleic acid fragments of a sequence selected from SEQ ID NO:14 through SEQ ID NO:26, and SEQ ID NO:49.

Group IX, claim(s) 93, 95, 97 an 98, drawn to a special technical feature of a polynucleotide sequence comprising an at least 19 contiguous base pair nucleotide sequence from within a sequence selected from SEQ ID NO:27 through SEQ ID NO:44, SEQ ID NO: 50 through SEQ ID NO:62, and SEQ ID NO: 72 through 76.

5. Claims 32-98 encompass hundreds RNA molecules which are considered to be unrelated because the RNA molecules in the claims do not have unity as set forth in *In re* Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group: (1) share a common utility, **and** (2) share a substantial structural feature essential to that utility. In the instant case, although some RNA molecules may share a common utility they do not meet the second prong of the test set out in *In re* Harnish (Id.) which requires that the sequences must also share a substantial structural feature disclosed as being essential to that

utility. As such, each RNA molecules in the claims is considered a patentably distinct invention.

6. In view of the basic requirement for the method, Applicant is required to elect two RNA molecules by SEQ ID NOs if any of Groups I-IX is elected. Please note: it is not species election.

7. Applicant is reminded, however, that other sequences could be rejoined if Applicant points out they share same sequence substantially.

8. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

10. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

9. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

10. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Bo Peng/
Patent Examiner
June 6, 2008